SUCTION UNIT NEW ASKIR 230 12V BR

USER MANUAL

CE 0123

NEW ASKIR 230/12V BR Surgical Aspirator is a portable unit designed for the aspiration of bodily fluids in adults and children.
It is particularly suitable for nasal, oral and tracheal aspiration of mucus, catarrh or blood after minor surgical procedures and can be used in post-
operative therapy at home or conveniently transported from one hospital ward to another.
The device operates on a 230V ~ AC 12V DC mixed power supply and is designed for virtually continuous use. This is made possible by an advanced
electronic system that manages the power supply and enables the unit to operate even while the battery is being charged.
The LED lights on the front control panel signal when the unit is operating, as well as the charge and re-charge status of the batteries.
The New Askir 230/12V Br comes equipped an aspiration regulator on the front panel and a polycarbonate autocavable jar complete with overflow valve.
It's made of a highly heat-resistant electrically insulated plastic material that conforms with the latest European safety standards.

GENERAL WARNING

READ INSTRUCTION MANUAL CAREFULLY BEFORE USE

ONLY HIGHLY QUALIFIED STAFF USE RESERVED

THE INSTRUMENT MUST NOT BE DISASSEMBLED. FOR A TECHNICAL SERVICE ALWAYS CONTACT CA-MI

IMPORTANT SAFETY RULES

1. Check the condition of the unit before each use. The surface of the unit should be carefully inspected for visual damage.
Check the mains cable and **don't connect to power** if damage is present.
2. Before connecting to power, always check the manufacture's label to ensure the electrical design of the unit and style of plug comply with the
electrical network to be used.
3. If the plug supplied with the appliance is incompatible with the mains electricity socket, contact qualified staff for replacement of the plug with a
suitable type. The use of simple or multiple and / or extension adapters is not generally recommended. Whenever their use is indispensable, use
those in compliance with safety regulations, however paying attention not to exceed the maximum power supply limits, which are indicated on the
adapters and extensions.
4. Pay special attention to the following:
· Only use original accessories and components;
· The device can be used only with the bacteriological filter;
· Never immerse the appliance into water;
· Position the appliance on flat stable surfaces;
· Position the device in a way that the air inlets on the back aren't obstructed;
· Never use the device in environments which have anaesthetic mixtures inflammable with air, oxygen or nitric oxide;
· Don't touch the device with wet hands and always prevent the appliance coming into contact with liquids;
· Keep off the reach of children or not capable people without supervision;
· Don't leave the appliance connected to the power supply socket when not in use;
· Hold plug to remove from socket. Don't pull on cable
· Preserve and use the medical device in environments protected from atmospheric factors and at a distance from heat sources.
· Don't use the device thoracic drainage.
5. For repairs, exclusively contact CA-MI technical service and request the use of original spare parts. Failure to comply with the above can jeopardise
the safety of the device.
6. **This medical device must be destined exclusively for the use for which it has been designed and described in this manual.**
Don't use for anything other than the use defined by the manufacturer. The manufacturer will not be responsible for damage due to improper use or
connection to an electrical system not complying with current regulations.
7. The device is intended for use in the electromagnetic environment outlined in this manual. Install and use as directed.
8. Instrument and accessories discharging must be done following current law regulations in every country of use.

9. The lead battery integrated in the device is not to be considered as an ordinary domestic waste. Such a component must be disposed of in a
specific collection centre in order to be recycled.
10. None of electric or mechanical parts have been designed to be repaired by customers or end-users. Don't open the device, do not mishandle the
electric / mechanical parts. Always contact technical assistance
The manufactured cannot be held liable for accidental or indirect damages should the device be modified, repaired without
authorization or should any of its component be damaged due to accident or misuse.
Any minimal modification / repair on the device voids the warranty and does not guarantee the compliance with the technical
requirements provided by the MDD 93/42/EEC (and subsequent changes) and its normatives.

IMPORTANT INFORMATION FOR CORRECT DISPOSAL OF THE PRODUCT IN ACCORDANCE WITH EC DIRECTIVE 2002/96/EC:

In respect of art. 13 Decreto Legislativo 25 Luglio 2005, n.151 "Actuation of European directives 2002/95/EC, 2002/96/EC and 2003/108/EC, for reduction in use of dangerous substances in the electric and electronic device and for garbage disposal"
The symbol as over applied on the device or its packaging means that at the end of its useful life the product must not be disposed of with domestic waste. At the end of device useful, the user will must deliver it to the able collecting centres for electric and electronic garbage, or give back to the retailer in the moment of equivalent new device purchasing, one against one. Disposing of the product separately prevents possible negative consequences for the environment and for health, deriving from inadequate disposal. It also allows the recovery of materials of witch it's made up in order to obtain an important saving of energy and resources and to avoid negative effects to the ambient and health. In case of abusive disposal of device by user, will be applied administrative endorsements in compliance with current standard.

TECHNICAL CHARACTERISTICS

TYPOLOGY (MDD 93/42/EEC)	Dispositivo Medico Classe IIa
MODEL	**NEW ASKIR 230/12V BR**
CLASSIFICATION UNI EN ISO 10079-1	HIGH VACUUM / LOW FLOW
POWER FEEDING	230V~ / 50Hz or Internally powered equipment (PB Battery 12V 3Ah) or 12Vdc (1.9A) from car battery
POWER CONSUMPTION	50VA
FUSE	F 1 x 630mA 250V
MAXIMUM SUCTION PRESSURE (without jar)	-75kPa (-0.75 Bar) from -75kPa (-0.75bar) to -10kPa (-0.10 bar)
MAXIMUM SUCTION FLOW (without jar)	16 l/min
WEIGHT	4.9Kg
SIZE	350 x 210 (h) x 180 mm
DUTY CYCLE (to 35°C and 110% operating voltage)	NON-STOP OPERATED
SICILICONE TUBE SIZE	Ø 6 x 10 mm
ACCURANCY OF VACUUM INDICATOR	± 5%
WORKING CONDITION	Room temperature: 5 ÷ 35°C Room humidity percentage: 30 ÷ 75% RH Altitude: 0 ÷ 2000m s.l.m.
CONSERVATION CONDITION AND TRASPORT	Room temperature: -40÷ 70°C Room humidity percentage: 10 ÷ 100% RH

SYMBOLS	
	Class II isolation equipment
CE 0123	CE marking in conformity with EC directive 93/42/EEC and subsequent changes
	Warning, consult the instruction manual
	Keep in a cool, dry place
	Conservation temperature: -40 ÷ 70°C
	Type B equipment
	Fuse
	DEHP Phthalates (Suction catheter)
~	Alternate Current
Hz	Mains Frequency
I	ON
O	OFF

Please note technical specifications may vary upon the manufacturer's discretion!

Guidance and manufacturer's declaration – Electromagnetic Emissions		
The surgical aspirator **NEW ASKIR 230/12V BR**is intended for use in the electromagnetic environment specified below. The customers or the user of the surgical aspirator **NEW ASKIR 230/12V BR** should assure that it's used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
Power disturbance CISPR11	Group 1	The surgical aspirator **NEW ASKIR 230/12V BR** only used RF energy only for its internal functioning. Therefore its RF emissions are very low and are not cause interference in proximity of any Electronic appliances.
Irradiated / Conducted emissions CISPR11	Class [B]	The surgical aspirator **NEW ASKIR 230/12V BR** can be used in all environments, including domestic and those connected directly to the public mains distribution that supplies power to environments used for domestic scopes.
Harmonic emissions IEC/EN 61000-3-2	Class [A]	
Voltage fluctuations / flicker emissions IEC/EN 61000-3-3	Complies	

Guidance and manufacturer's declaration – Electromagnetic Immunity		
The surgical aspirator**NEW ASKIR 230/12V BR** is intended for use in the electromagnetic environment specified below. The customers or the user of the surgical aspirator **NEW ASKIR 230/12V BR** should assure that it's used in such an environment.		
Immunity Test	**Compliance**	**Electromagnetic environments - guidance**
Electrostatic discharge (ESD) IEC/EN 61000-4-2	± 6kV on contact ± 8kV in air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / burst IEC/EN 61000-4-4	± 2kV power supply	Mains power quality should be that of a typical commercial environment or hospital
Surge IEC/EN 61000-4-5	± 1kV differential mode	Mains power quality should be that of a typical commercial environment or hospital
Loss of voltage, brief voltage interruptions and variations IEC/EN 61000-4-11	5%U_T for 0.5 cycle 40%U_T for 05 cycle 70%U_T for 25 cycle <5%U_T for 5 sec	Mains power quality should be that of a typical commercial environment or hospital If the user of the surgical aspirator NEW ASKIR 230/12V BR request that the appliance operates continuously, the use of a continuity unit is recommended.
Magnetic field IEC/EN 61000-4-8	3A/m	The power frequency magnetic field should be measured in the intended installation location to assure that it's sufficiently low.
Conducted Immunity IEC/EN 61000-4-6	3Vrms 150kHz to 80MHz (for appliances that aren't life - supporting)	-
Irradiated Conducted IEC/EN 61000-4-3	3V/m 80MHz to 2.5 GHz (for appliances that aren't life - equipment)	-
Note U_T is the value of the power supply voltage		

ACCESSORIES SUPPLIED

DESCRIPTION
COMPLETE ASPIRATION JAR 1000cc
CONICAL FITTING
TUBES SET 6 mm x 10 mm
ASPIRATION PROBE CH20
ANTIBACTERIAL FILTER

Antibacterial Filter: The filter is produced with (PTFE) hydrophobic material to prevent fluids entering the pneumatic circuit. It should be changed immediately if it becomes
wet or if there is any sign of contamination or discolouration. If should also be changed if the unit is used with a patient whose risk of contamination is
unknown. **Don't use the suction unit without the protection filter**. If the suction unit is used in an emergency or in a patient where the risk of
contamination is not know the filter must be changed after each use. Available under request with different versions with complete jar 2000cc.
Suction catheter: Single-use device to be used on a single patient. Do not wash or re-sterilize after use.
Reuse may cause cross-infections. Don't use after lapse of the sell-by date

<u>WARNING:</u> Suction tubes for insertion in the human body purchased separately from the machine should comply with ISO 10993-1 standards on material biocompatibility.

CLEANING OF ACCESSORIES

To clean the plastic housing of the device wear disposable latex gloves and clean with denaturated alcohol or hypoclorite solutions.
Washing and / or cleaning the autoclavable jar as to be carried out as follows:

- Wear protection gloves and apron (glasses and face mask if necessary) to avoid contact with contaminating substances;
- Disconnect the jar from the device
- Disconnect all tubes from the jar and the protection filter
- Empty and dispose of the content and of the suction catheter according to the laws in force in your country;
- Separate all parts of the cover (overflow valve, o-ring);

After disposing of disposable parts and disassembling the jar wash in running cold water and rinse thoroughly.
Then soak in warm water (temperature shall not exceed 60°C).
Wash thoroughly and if necessary use a non-abrasive brush to remove incrustations.
Rinse in running warm water and dry all parts with a soft cloth (non-abrasive).
The jar and the cover can be autoclaved by placing the parts into the autoclave and running one sterilization stem cycle at 121°C (1 bar relative pressure) making sure that the jar is positioned upside down.
Mechanical resistance of the jar is guaranteed up to 30 cycles of sterilization and cleaning at the indicated conditions (EN ISO 10079-1). Beyond this limit the physical-mechanical characteristics of the plastic may decrease and replacement of the part is therefore recommended.

After sterilization and cooling at environment temperature of the parts make sure that these are not damaged.
Assemble the jar as follows:

- Place the overflow valve into its seat in the cover (under VACUUM connector)
- Insert floating valve keeping the o-ring towards the opening of the cage
- Place the o-ring into its seat around the cover
- After completing assembling operations always make sue that cover seals perfectly to avoid vacuum leakages or liquid exit

The aspiration tubes can be sterilized on autoclave using a sterilization cycle at 120°C.
The conical connector can be sterilized on autoclave using a sterilization cycle at 121°C.
The device is ready for a new employment now.

DO NOT WASH, STERILIZE OR PUT IN AUTOCLAVE THE ANTIBACTERIAL FILTER

MAINTENANCE

The **NEW ASKIR 230/12V BR** suction equipment does not need maintenance or lubrication.
It is, however to inspect the unit before each use. Unpack the instrument and **always check** integrity of plastic parts and feeding cable, they might have been damaged during previous use. Connect cable to electrical network and turn switch on.
Close the aspirator outlet with your finger and with suction regulator in maximum vacuum position check that the vacuum indicators reaches
– 75 kPa (-0.75 bar) minimum (internal battery). Rotate the knob from right to left and check the aspiration regulating control.
The vacuum indicator should go down – 40 kPa (-0.40 bar). Verify that loud noises are not present, these can indicate wrong functioning.
The equipment may also be used with the power cord hooked up to the electricity mains (the yellow light switches over to the fixed green light).
Ensure that the green light comes on and that, after a few seconds it switches over to the yellow light (meaning that the charged battery is operating).
A protection fuse (**F 1 x 630mA 250V**) reachable from exterior and it situated in the plug protects the instrument.
For fuse replacing, always the type and the range. The device is made up of a lead battery which cannot be accessed by outside. In order to replace
consult the technical staff authorised by the manufacturer.

Fault type	Cause	Solution
1. Red light on	Battery run down	Hook up the power cord to the electricity mains, positioning the equipment power switch on 0. Charge it for 8 hours, until the yellow light switch over to the green light.
2. Red light on	Battery run down	The device may be also be supplied by an power cord hooked up to the electricity mains: the yellow light comes on and then switch over to the green light.
3. No aspiration	Jar Cap badly screwed down	Unscrewed the cap, then rescrew it correctly
4. No aspiration	Lid seal not in its seat	Unscrew the cap and insert the seal properly in its seat
5. The float doesn't close	If the cap has been washed, ensure that the float is not partially detached	Insert the float into it's place
6. The float doesn't close	The float it's covered by dirty material	Unscrewed the cap, leave the and put in on autoclave
7. Low suction	Foam inside the jar	Fill the jar to 1/3 full of ordinary water
8. No aspiration due to flow leakage of mucus	Filter blocked	Replace filter
9. The Vacuum power on the patient side is either very low or absent	· Vacuum regulator set to minimum · Protection filter blocked or damaged · Connection tubes blocked, kinked or disconnected · Shut-off valve blocked or damaged · Pump motor damaged	· Turn the vacuum regulator clockwise and check the value of the vacuum on the gauge · Replace the filter · Replace or reconnect the tubes, check the jar connections · Empty the jar, or disconnect the tube from the jar and unblock the shut-off valve. The unit twill only work in the upright position · Refer to authorised service personnel
Faults 1 - 2 - 3 - 4 - 5 - 6 - 7	**None of the remedies has achieved the desired results**	**Contact the seller or CA-MI After-sales Assistance Service**

If the overfill security system fails, continued aspiration will be stopped by the bacteriological filter.
Should this back-up security also fail, there is a risk of penetration of liquid into the device. Don't attempt to proceed with aspiration under these circumstances. Return the device to CA-MI for service.

BEFORE EVERY CHECKING OPERATION, IN CASE OF ANOMALIES OR BAD FUNCTIONING, PLEASE CONTACT CA-MI TECHNICAL SERVICE. THE MANUFACTURER DOES NOT GIVE GUARANTEE IF INSTRUMENT, AFTER THE TECHNICAL SERVICE CHECKING, APPEARS TO BE TAMPERED.

INSTRUCTIONS

· Place the unit on a flat, horizontal surface.
· Connect the short silicon tube, with antibacterial filter, to the suction connector . The other tube, with one end connected to the antibacterial
filter with the other end to jar's lid connector where has been fixed the red float. When the 90% of the volume of the jar is reached there is the
activation of the security float (the float close the aspiration connector on the jar) to the avoid liquid penetration inside the device.
· Connect the long silicon tube to the other jar's lid connector
· Connect the other end of the long silicon tube to the probe plastic connector then connect the suction probe to it.
· Connect the power cord to the device then connect the plug to the electrical mains supply.
· Push switch on position **I** to start suction
· Unscrew the jar's lid and fill the jar 1/3 full or ordinary water (this for an easy cleaning operations and an rapid reaching of the functionally vacuum)
then rescrew the lid on the jar correctly.
· Once finished push switch on **0** position and unplug.
· To extract the accessories and start with cleaning.

WARNING: Ensure that the FLUID SIDE or IN marker on the filter is on the side facing the collection jar lid and fitted into the "VACUUM".A wrong connection causes immediate destruction in case of contact with sucked liquids.

Battery functions
The internal battery provides 45 to 50 minutes of continuous use.
After use, the unit must be recharged for 120 to 150 minutes. A standard cycle would be to use the equipment for 45 minutes and then recharge it for 120
minutes. A complete recharge takes 8 hours.
To recharge, connect the power cable to a 230V outlet and ensure the power switch on the unit is turned on.
Battery function is indicated by the LED lights at the top right of the unit.
The green LED is on if either the battery is fully charged or the mains power has been connected. The yellow LED indicates the unit is charging.
The red LED indicates the battery is fully discharged.

NEVER USE THE DEVICE WITHOUT JAR AND / OR PROTECTION FILTER
MAKE SURE THAT CHILDREN AND/OR MENTALLY ILL PEOPLE DO NOT USE THE DEVICE WITHOUT ADULT SURVEILLANCE

ALWAYS PLACE THE DEVICE IN POSITIONS FOR EASY DISCONNECTION.

RULES FOR RETURNING AND REPAIRING

COMPLYING WITH THE NEW EUROPEAN RULES, CA-MI INDICATES THE IMPORTANT POINTS TO PROTECT INSTRUMENT AND OPERATORS HYGIENE.

THESE RULES MUST BE RESPECTED IN ORDER TO GUARANTEE HYGIENE AND SAFETY TO ALL THE PEOPLE OPERATING WITH THE INSTRUMENT TO OBTAIN QUALITY AND WELL BEING.

CA-MI warrants it's products for **24 months** after purchasing date.
In front of this warranty, CA-MI will be obliged only to repair or substitute free of charge the products or parts of them that, after verification effected on our factory, or our authorized Service Center, by the Technical Service, results defective.
The product must be accompanied by a description of the defect.

The warranty, with exclusion of responsibility for direct and indirect damages, it is thought limited to the solos defects of material or workmanship and it stops having effect when the device results however gotten off, tampered or sheltered out of the Factory or from the Authorized Service center.
The commodity always travels to risk and danger of the buyer, without any responsibility of CA-MI for damages caused by the transport or dismay from the vector.
Every returned instrument will be hygienically checked before repairing. If CA-MI finds instrument not suitable for repairing due to clear signs of internal or external contamination, the same will be returned to customer with specification of NOT REPAIRED INSTRUMENT, accompanied by an explanation letter.
CA-MI will decide if contamination is due to bad functioning or misuse. If contamination is due to bad functioning, CA-MI will substitute the instrument, only if a SALE RECEIPT and STAMPED GUARANTEE accompany the same.
CA-MI is not responsible for contaminated accessories, they will be substitute at customer's expenses.

For this reason it is **COMPULSORY** to carefully disinfect the external part of the instrument and accessories with a cloth soaked in methylated spirits or hypochlorite-based solutions. Put the instrument and accessories in a bag with indication of disinfecting.
We also request to specify the kind of fault, in order to speed up repairing procedures.
To this end, please read the instructions carefully in order to avoid damaging the equipment through improper use.

Always specify the fault encountered so that CA-MI can establish whether it falls into the category of the faults covered by the guarantee.

CA-MI Srl cannot be held liable for accidental or indirect damages should the device be modified, repaired without authorization or should any of its component be damaged due to accident or misuse.
Any minimal modification / repair on the device voids the warranty and does not guarantee the compliance with the technical requirements provided by the MDD 93/42/EEC (and subsequent changes) and its normatives